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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/522,336 03/09/2000 Carlos F. Vonderwalde 24079-1080 3266 7590 12/04/2003 EXAMINER EDWARD J. LYNCH HO, UYEN T **DUANE MORRIS LLP** ART UNIT PAPER NUMBER ONE MARKET SPEAR TOWER, SUITE 2000 3731 SAN FRANCISCO, CA 94105

Please find below and/or attached an Office communication concerning this application or proceeding.

,	Application No.	Applicant(s)
Office Action Summary	09/522,336	FREIDBERG ET AL.
	Examiner	Art Unit
	(Jackie) Tan-Uyen T. Ho	3731 [].
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status		
1) Responsive to communication(s) filed on 17 November 2003.		
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 16,18-22 and 48-50 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>16,18,19,21,22,48 and 50</u> is/are rejected.		
7)⊠ Claim(s) <u>20 and 49</u> is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. §§ 119 and 120		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific</li> </ul>		
reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.		
Attachment(s)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) 🔲 Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)
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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2003 has been entered.
- 2. The amendment filed 11/18/2003 has been entered and fully considered but it does not place the application in condition for allowance. New rejection grounds are as follow.

#### Claim Objections

3. Claim 49 is objected to because of the following informalities: In line 3, "the tubular stent body ring section" should be "the tubular stent body". Appropriate correction is required.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 16, 22, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleshinski (5,755,778).

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Kleshinski discloses a stent assembly including an expandable tubular stent (figs. 5-7) having a body having a plurality of undulation ring sections and connecting support member extending between adjacent ring sections, a cover connecting member (74) formed integral with the connecting support member (figs. 5-7), a plurality of ring connectors extend between adjacent ring sections and a biocompatible stent cover (24, col. 3, lines 14-17) disposed over the body wherein the cover connecting member including a penetrating element extending through and over an outer surface of the stent cover (col. 5, lines 63-67) and wherein the cover being made from biocompatible material PTFE (col. 3, lines 12-20).

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleshinski (5,755,778) in view of Khosravi et al. (5,824,054).

In regard to claim 18 and 19, although Kleshinski does not disclose the cover including having two longitudinally oriented edges overlapping each other, attention is directed to the Khosravi et al. reference which discloses a stent cover having two longitudinally oriented edges overlapping each other. Therefore, it would have been obvious matter of design choice to modify the Kleshinski

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reference by having the cover being made from a sheet including two longitudinally oriented edges wrapping around the stent or by a tubular sheath disposed about the stent, since applicant has not discloses that having the cover having two longitudinally oriented edges solves any stated problem or is for any particular purpose and it appears that the cover would perform equally well in a sheet configuration including two longitudinally oriented edges or in any other tubular shape configuration.

In regard to claim 21, although, Kleshinski does not disclose the cover covering end to end of the stent, attention is directed to the Khosravi et al. reference which discloses a stent cover covering end to end of the stent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the cover of Kleshinski having a length extending from end to end of the stent in order to completely cover the stent as one desired.

### Allowable Subject Matter

8. Claims 20 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In regard to claim 20, the prior fails to disclose in combination with other limitations of the claim, a cover-connecting member having two penetration elements. In regard to claim 49, the prior fails to disclose undulations of at least one ring section extend over an end portion of the stent cover.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

(Jackie) Tan-Uyen T. Ho Patent Examiner Art Unit 3731

November 28, 2003